

National Organic Materials Update

Daniel Giacomini, Chairperson
Materials Committee – NOSB
NOSB Public Meeting, November 2007

Outline

- National List of Allowed and Prohibited Substances
- Petitioned and Sunset Review Items
- NOSB Material Review Process
- National List Criteria
- Sunset Review Criteria
- Definition of Materials
- Final Notes

National List of Allowed and Prohibited Substances

Crops

§ 205.601 Synthetic substances allowed for use in organic crop production.

§205.602 Nonsynthetic substances prohibited for use in organic crop production.

Livestock

§205.603 Synthetic substances allowed for use in organic livestock production.

§205.604 Nonsynthetic substances prohibited for use in organic livestock production.

Handling (605)

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specific ingredients or food group(s))”.

(a) Nonsynthetics allowed

(b) Synthetics allowed

Handling (606)

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as organic.

Petitioned & Sunset Review Items

Petitioned Items– Fall 2007 Recommendations

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| <p>601</p> <ul style="list-style-type: none"> • Potassium silicate • Sodium carbonate peroxyhydrate • Sodium ferric hydroxy-EDTA | <p>606</p> <ul style="list-style-type: none"> • Grape seed extract |
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Sunset Items– Fall 2007 Recommendations

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| <p>601</p> <ul style="list-style-type: none"> • Copper sulfate (2) • Ozone gas • Peracetic acid (2) • EPA List 3 inerts <p>602</p> <ul style="list-style-type: none"> • Calcium chloride | <p>605a</p> <ul style="list-style-type: none"> • Agar-agar • Caraageenan • Tartaric acid • Animal Enzymes • Calcium sulfate • Glucono delta-lactone <p>605b</p> <ul style="list-style-type: none"> • Cellulose |
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Petitioned Items– Fall 2007 Consideration

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| <p>601</p> <ul style="list-style-type: none"> • Cheesewax • Sodium hypochlorite, acidified <p>603</p> <ul style="list-style-type: none"> • Fenbendazole <p>605a</p> <ul style="list-style-type: none"> • Calcium from seaweed <p>605b</p> <ul style="list-style-type: none"> • Gellan gum | <p>606</p> <ul style="list-style-type: none"> • Chinese thistle daisy • Black pepper • Camu Camu Extract Powder • Carmel Color • Chickory Root Extract • Codonopsis Root Extract • Ginger Root Extract • Jujube Fruit Extract • Marsala Cooking wine • Peony Root Extract • Polygala Root Extract • Poria Fungus Extract • Rehmannia Root Extract • Sherry Cooking wine • Tangerine Peel Extract |
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Petitioned Items – Fall 2007 Additional

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| <p>Returned to NOP and waiting for additional information</p> <ul style="list-style-type: none"> • Dextrin • Propionic acid • Sorbitol octanoate | <p>Deferred by petitioner (no additional action or consideration at this time)</p> <ul style="list-style-type: none"> • Ammonium Salts of FA • Pelargonic acid • Sulfuric acid • Yeast |
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Livestock – Fall 2007

No petitioned or sunset items are on the docket for the Livestock Committee for this fall.

Methionine: nature of annotation with an end date makes this item not eligible for sunset – this substance must be petitioned to stay on the National List.

NOSB Material Review Process

NOSB Material Review Process

- The minimum timeframe for National List Material Review is 145 days.

NOSB Material Review Process

Day 1 through 14:

- Petition received by NOP & reviewed for completeness.
- Upon determination of completeness by the NOP, petition forwarded to NOSB Materials Chairperson.

NOSB Material Review Process

Day 14 through 21:

- The Materials Chairperson forwards petition to the Chairperson of the designated NOSB committee (ie. Crops, Livestock, or Handling).
- Petition is re-evaluated for completeness and to determine if it will be forwarded for a TAP review (no TAP for 606 items).

NOSB Materials Review Process

Sixty (60) days prior to the NOSB Meeting:

- TAP reviews sent to NOSB.
- TAP reviews posted on the NOP website for review and public comment.
- Committee recommendations posted for public comment.
- Within the 30 days prior to the meeting, public comment is accepted by the NOP and posted on the website.

NOSB Materials Review Process

At the NOSB Meeting:

- Committee recommendations are submitted.
- Further comments are accepted from the public and all public comments are taken into consideration.
- Action is taken by the full NOSB board regarding committee recommendations.

NOSB Materials Review Process

During the entire process:

- All communication between petitioners and the NOSB should go through the NOP.

National List Criteria

National List Criteria General

- (1) The potential of such substance for detrimental chemical interactions with other materials used in organic farming systems;
- (2) The toxicity and mode of action of the substance and of its breakdown products of any contaminants, and their persistence and areas of concentration in the environment;

National List Criteria General

- (3) The probability of environmental contamination during manufacture, use, misuse, or disposal of such substance;
- (4) The effect of the substance on human health;

National List Criteria General

- (5) The effect of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

National List Criteria General

- (6) The alternatives to using the substance in terms of practices or other available materials; and
- (7) Its compatibility with a system of sustainable agriculture.

--Federal Register [Docket Nos. AMS-TM-06-0223; TM-06-12]

National List Criteria Processing Aid or Adjuvant

- (1) The substance cannot be produced from a natural source and there is no organic substitute;
- (2) The substance's manufacture, use and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;

National List Criteria Processing Aid or Adjuvant

- (3) The nutritional quality of the food is maintained when the substance is used, and the substance itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations;

National List Criteria Processing Aid or Adjuvant

- (4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;

National List Criteria Processing Aid or Adjuvant

- (5) The substance is listed as generally recognized as safe (GRAS) by Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; and
- (6) The substance is essential for the handling of organically produced agricultural products.

--§205.600 (b)

National List Criteria 606 – Agricultural and Potentially Commercially Unavailable

The NOSB will consider:

- (A) Why the substance should be permitted in the production or handling of an organic product;

**National List Criteria
606 – Agricultural and Potentially
Commercially Unavailable**

- (B) The current industry information regarding availability of and history of unavailability of an organic form in the appropriate form, quality, or quantity of the substance.

**National List Criteria
606 – Agricultural and Potentially
Commercially Unavailable**

- (B, cont.) Industry information includes, but is not limited to the following:
 - (1) Regions of production, including factors such as climate and number of regions;
 - (2) Number of suppliers and amount produced;

**National List Criteria
606 – Agricultural and Potentially
Commercially Unavailable**

- (3) Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;

**National List Criteria
606 – Agricultural and Potentially
Commercially Unavailable**

- (4) Trade related issues such as evidence of hoarding, war, trade barriers or civil unrest that may temporarily restrict supplies; and
- (5) Other issues which may present a challenge to a consistent supply.

--Federal Register [Docket Nos. AMS-TM-06-0223; TM-06-12]

**Sunset Review
Criteria**

Sunset Review Criteria

Sunset Provision-No exemption or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 yrs of such exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition.

-OFPA §2118(e)

Sunset Review Criteria

- Sunset includes the opportunity to revisit the continued need for the regulation, and
- If a review finds that the initial conditions still exist, the regulation is renewed for an additional period of time.

Sunset Review Criteria

- The sunset process is not
 - Used to petition to add new substances to the NL,
 - Nor is it used to change an existing annotation.

Sunset Review Criteria

- Exemptions (NL listings) were accepted because the evidence available showed
 - Substances were found not harmful to human health or the environment,
 - the substances were necessary because of the unavailability of wholly nonsynthetic alternatives, and
 - the substances were consistent and compatible with organic practices.

Sunset Review Criteria

- Sunset is a repeat of the NL process.
- NOSB must solicit information and comment to reevaluate the substances against the same criteria.
 - Substances were found not harmful to human health or the environment,
 - the substances were necessary because of the unavailability of wholly nonsynthetic alternatives, and
 - the substances were consistent and compatible with organic practices.

-NOSB Guidance Document "Sunset and the National List of Allowed and Prohibited Substances" Adopted Oct 14, 2004

Definition of Materials

Definition of Materials

"The art of simplicity simply means making peace with your complexity."

--India Arie
"Wings of Forgiveness"

Final Notes

Public Comment

- All public comments handled via www.regulations.gov according to the appropriate Federal Register docket and governmental agency.
- Effort to bring processing of public comment to equal level of efficiency for all departments and agencies.
- New process sets deadline for having public comment posted.
- All public comment received by the NOP will be made available to the NOSB members for review in advance of the respective vote, whenever possible.

Website Listings

- NOP: www.ams.usda.gov/nop/
- NOSB: www.ams.usda.gov/nosb/
- Public comment: www.regulations.gov